Root Cause Analysis for Pap Test Diagnostic Errors Due to Sampling Using A Lean Production System Improves Specimen Quality

Stephen S. Raab, MD,[a] Carey Andrew-JaJa, MD,[b] Jennifer L. Condel, BS, SCT(ASCP)MT,[a] and Colleen Vrbin, BS[a]

University of Pittsburgh School of Medicine, Department of Pathology [a] and Obstetrics and Gynecology,[b] University of Pittsburgh Medical Center, Pittsburgh, PA

Abstract

Objective: To determine if the Toyota Production System (TPS) process improves Pap test quality and patient safety.
Study design: We performed an 8 month non-concurrent cohort study that included 464 case and 639 control women who had a Pap test. We redesigned office workflow using TPS methods by introducing a one-by-one continuous flow process. We measured the frequency of Pap tests without a transformation zone component, follow-up and Bethesda System diagnostic frequency of *atypical squamous cells – undetermined significance (ASC-US)*, and diagnostic error frequency.
Results: After the intervention, the percentage of Pap tests lacking a transformation zone component decreased from 9.9% to 4.7% (P = .001). The percentage of Pap tests with a diagnosis of *ASC-US* decreased from 7.8% to 3.9% (P = .007). The frequency of error per correlating cytologic-histologic specimen pair decreased from 9.52% to 7.84%.
Conclusions: The introduction of the TPS process resulted in improved Pap test quality.

Introduction

In the past decade, a number of technological advances (e.g., liquid based preparations, automated screening, and human papillomavirus (HPV) testing) have been applied to cervical cancer screening in order to improve Pap test sensitivity. Theoretical cost effectiveness studies predict that application of these technologies will result in fewer cervical cancer deaths, although these technologies increase the average cost of the Pap test by $30 to $180.
Meta-analyses showed that the sensitivity of the Pap test (prior to the introduction of newer technologies) was approximately 58%, and that most false negatives were secondary to clinical sampling (i.e., failure to adequately obtain material from the diseased area). In general, methods to decrease sampling error have not focused on practice changes. Paradoxically some technologies, such as liquid-based technologies, increase Bethesda System diagnoses of *atypical squamous cells-undetermined significance* (*ASC-US*), a category that partly exists because of failures in clinical sampling.
Quality assurance methods that long have been successfully operative in industry currently are being applied to healthcare. In this study, we utilized the Toyota Production System (TPS), a type of lean production system, to address Pap test quality. Lean production methods focus on improving workflow design, with the ultimate goal being a one-by-one, continuous flow practice.

Materials and Methods

Quality Improvement Method

The literature on quality improvement generally is lacking on how interventions successfully may be implemented. In this study, we used a 6-step process that involved choosing a target for improvement, problem analysis, intervention design, pretest, implementation, and evaluation.

Toyota Production System

We developed an error-reduction intervention that targeted improving Pap test sampling. We chose to implement changes in the office of a single gynecologist who expressed enthusiasm about improving his Pap test sampling and fostering a better pathology-clinical relationship.
We implemented changes based on TPS principles of work redesign, which simultaneously focus on improving quality, reducing inefficiencies, and decreasing costs. We created a one-by-one process in which increased attention was placed on the individual patient and her Pap test. Practitioners normally go through a step-wise procedure during Pap test procurement. For example, practitioners examine the cervix, note abnormalities, and obtain diagnostic material using generally specified methods. However, with the passage of time, many of the tasks they perform become rote and practitioners may bypass steps.
Prior to implementation, a process improvement team met with the gynecologist to determine how TPS principles should be introduced. These individuals designed a checklist that would focus attention on every step in the Pap test procurement process (Table 1). The goal was to obtain a "perfect" Pap test for every patient, and from the clinical standpoint, this meant obtaining a satisfactory specimen that adequately sampled the transformation zone, the area in which preneoplastic lesions usually develop.
An immediate feedback loop was created so that the gynecologist could correlate his clinical impression with the diagnostic findings. If the gynecologist thought that the Pap test was either *fair* or *poor*, the cytotechnologist immediately faxed her diagnostic findings related to the presence of a transformation zone component (TZC) and specimen limitations. The cytotechnologist also faxed her results in which she made a diagnosis of *unsatisfactory* or *absent* TZC.
Using data from 2003, we compared this gynecologist with all other providers, in order to determine if this provider was an outlier in any quality measure (Table 2). Measures of quality were Pap test adequacy, frequency of specific Bethesda System diagnostic categories, and frequency of diagnostic error (based on the cytologic-histologic correlation process). For Pap test adequacy, we classified Pap test diagnoses into the categories of *satisfactory* and *unsatisfactory* for interpretation. For *satisfactory* Pap tests, we determined if the TZC was *present*, *absent*, or *indeterminate*.
Table 2 divides all providers (n = 355) based on the annual number of Pap tests collected in 2003. Table 3 shows the frequency of specific Bethesda System diagnoses of select providers.

Timeframe

The TPS implementation was started on March 19, 2004 and data included in this analysis was collected until November 18, 2004. For comparison, we collected retrospective consecutive case data from the previous year for the same timeframe.

Quality Measures

For the case and control cohorts, we compared Pap test adequacy by comparing frequencies of *satisfactory* and *unsatisfactory*. For women with *satisfactory* Pap tests, we compared frequencies of *present*, *absent*, and *indeterminate* TZC. We also compared Bethesda System diagnostic frequencies and specifically compared the frequency of the diagnosis of *ASC-US*. We compared case and control cytologic-histologic correlation discrepancy frequencies.

Statistical Analysis

Statistical significance was assumed at a $P <= .05$. Transformation zone and Bethesda System diagnostic category frequency initially were evaluated using descriptive statistics. Differences between case and control cohort transformation zone and diagnostic category frequency were examined using the Chi-square test.

Results

For Pap tests obtained during the pre-intervention and intervention timeframes, the frequency of the Bethesda System diagnosis of *absent* TZC was 9.86% and 4.74% (P = .001), respectively (Table 4). For the pre-intervention and intervention timeframes, the number of *unsatisfactory* Pap tests was 4 and 5, respectively; this increase was not statistically significant.
When all Pap test diagnoses were re-classified as *NILM*, *atypical*, and *SIL*, there was a statistically significant difference in category use between the pre-intervention and intervention timeframes (P = .023) (Table V). This shift in Bethesda System diagnoses resulted in more Pap tests being diagnosed as *NILM*; the percentage of women with a *SIL* Pap test diagnosis remained the same. The percentage of Pap tests diagnosed as *ASC-US* decreased during the intervention timeframe from 7.8% to 3.9% (P = .008).
For the pre-intervention and intervention timeframes, the percentage of women who had an *ASC-US* diagnosis and had an HPV test were 94.4% and 88.0%, respectively. The percentage of women who had a positive high risk HPV test increased from 18.2% to 23.5%, although this trend was not statistically significant. The number of patients with cytologic-histologic diagnostic discrepancies for the pre-intervention and intervention timeframes was 4 (9.52% of all patient with correlating specimens) and 4 (7.84%), respectively. This decrease was not statistically significant, although the sample size was small and was not of sufficient power.

Table 1. Gynecology and cytology checklists

Gynecology Checklist

Specimen Collection
Visualization of cervix: O Yes O No
Limitations of visibility: O Menstruating O Profuse Discharge/Mucus O Other _____
Cleaned Cervix: O Yes O No
Visualization of Transformation Zone: O Yes (entire) O Partial O No
Diameter of cervix: O 0-2 O 2-4 O >4
***Sampling device used and the number of clockwise rotations over transformation zone:**
O Cytobroom (Number____)
O Cytobrush (Number____)
O Spatula (Number____)
Comments about sampling device(s) used: _____
***Specimen Type:** O ThinPrep® (Number of vigorous rotations in vial ___) O Conventional
Visualization of abnormality: O Yes O No
***Adequate Cellularity:** O Good O Fair O Poor
If poor, why: O Stenosis O Bleeding O Atrophy O Pain
Additional Comments: _____
***Complete for Hysterectomy Patients**

Cytology Checklist

Accession Number: _____
Visual appearance of ThinPrep® vial: O Cellular O Low cell O Bloody
Presence of Transformation Zone: O Yes, EC O Yes, SM O No
Quantify Squamous Component: O Borderline O Adequate
Adequate Sample: O Yes O No, due to_____
Additional Comments: _____

Table 2. Pap test adequacy by provider volume of Pap tests procured in 2003

Subclassification of providers by number of Pap tests collected	Satisfactory Pap tests (%)			Unsatisfactory Pap tests (%)	Number of Pap tests
	Presence of transformation zone				
	No	Yes	Indeterminate		
< 500	13.3	72.9	12.9	0.91	14,096
500 - 1000	13.0	70.9	15.2	0.88	13,122
Target provider	9.9	73.0	16.6	0.45	896
1000 - 1500	10.9	73.3	15.0	0.80	29,629
1500 - 2000	12.8	72.1	14.2	0.96	25,518
> 2000	13.4	68.5	17.2	1.02	17,711
Total	12.4	71.8	14.9	0.91	100,076

Table 3. Number of Pap tests in 2003 with specific Bethesda System diagnoses by select group of providers

	Number of Pap tests with specific Bethesda System diagnoses (%)							
Provider	Unsat	NILM	ASC-US	ASC-H	ACC	LSIL	HSIL	Total
Target	4 (0.45)	791 (88.2)	72 (8.04)	2 (0.22)	6 (0.67)	20 (2.23)	1 (0.11)	896
A	8 (0.69)	993 (85.6)	106 (9.14)	5 (0.43)	3 (0.26)	43 (3.71)	2 (0.17)	1160
B	2 (0.31)	855 (89.1)	74 (7.71)	5 (0.52)	6 (0.52)	18 (1.88)	2 (0.21)	960
C	17 (1.44)	1054 (89.6)	69 (5.86)	5 (0.42)	4 (0.34)	26 (2.21)	2 (0.17)	1177
D	4 (0.40)	885 (88.1)	69 (6.87)	4 (0.40)	0 (0)	40 (3.98)	3 (0.30)	1005
Total	906 (0.91)	85548 (85.5)	8866 (8.86)	503 (0.50)	266 (0.27)	3360 (0.39)	557 (0.56)	100076

Table 4. Presence of transformation zone pre-intervention and during intervention

Timeframe	Number of satisfactory Pap tests (%)			Number of unsatisfactory Pap tests (%)	Number of Pap tests
	Presence of transformation zone				
	Yes	No	Indeterminate		
Pre-intervention	466 (72.9)	63 (9.86)	106 (16.6)	4 (0.63)	639
Intervention	380 (81.9)	22 (4.74)	57 (12.3)	5 (1.08)	464

Table 5. Pap test diagnoses pre-intervention and intervention

Timeframe	Bethesda System diagnosis (%)							
	Unsat	NILM	ASC-US	ASC-H	ACC	LSIL	HSIL	Total
Pre-intervention	4 (0.63)	564 (88.3)	50 (7.82)	2 (0.31)	6 (0.94)	13 (2.03)	0	639
Intervention	5 (1.08)	428 (92.2)	18 (3.88)	2 (0.43)	2 (0.43)	7 (1.51)	2 (0.43)	464

Comments

These data indicate that introduction of the TPS process resulted in improved cervical cancer screening by improving Pap test sampling, reducing the number of equivocal Pap test diagnoses, and decreasing the number of errors, as detected by discrepancy analysis. These improvements were achieved with reorganization of workflow and without the introduction of new technology or additional costs. This study also illustrates how error data may be used to develop quality improvement initiatives. Success of our intervention depended on a systematic approach of developing a quality assurance program that moved research into practice.
Lied and Kazandijan reported that the Hawthorne effect formed the basis of some forms of quality improvement. By using external observations, workers exhibited increased internal commitment that resulted in continuous improved performance. This improvement was based on individual responsibility maintained by periodic reinforcement of behaviors that lead to better performance. In our study, the continued improvement at the end of 6 months indicated that changes in Pap test procurement processes had become more ingrained in provider behavior.

Funding/Support

This study was supported by a grant from the Jewish Healthcare Foundation and grant HS13321-01 from the Agency for Healthcare Research and Quality